

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1, 3, 5, 7, 9-14, 17, and 18 presently appear in this application, with claims 13 and 14 being withdrawn from consideration by the examiner, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1, 3, 5 and 7 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for an expression vector comprising the cDNA encoding icIL-1ra-II protein and the genomic DNA sequence (SEQ ID NO:1) that encodes a human growth hormone signal peptide, does not reasonably provide enablement for an expression vector comprising the cDNA encoding icIL-1ra-II protein and a growth hormone signal peptide genomic sequence. The examiner states that the specification fails to provide sufficient guidance and/or working examples on how to make and use an expression vector comprising a growth hormone signal peptide genomic DNA sequence other than the human growth hormone signal peptide genomic DNA sequence. This rejection is obviated by the amendment to claim 1 to recite that the growth hormone signal peptide genomic DNA sequence is limited to the genomic DNA sequence encoding a human growth hormone signal peptide.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1, 3, 5, 7, and 9-12 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is obviated by the amendments to the claims where claim 1 is amended to recite for a mixture of icIL-1ra-II proteins beginning at residue position +1 and +2 and claims 9-12 are amended to recite for "glycosylated" icIL-1ra-II.

Claims 1, 3, 5, 7, 9-12 and 17-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pecceu et al and Selden et al. in view of Colotta et al. This rejection is respectfully traversed.

Attached hereto is a page of a laboratory notebook in which the experimental results from sequence analysis shows that in the isolated mixture of icIL-1ra-II proteins the major icIL-1ra-II protein begins at residue position +2 followed by lesser amounts of icIL-1ra-II proteins beginning at residue positions +1 and +5. The disclosures and teachings of the cited and applied references do not make obvious a mixture of icIL-1ra-II proteins as recited in the present claims. Applicants reserve the right to file a declaration presenting these results with a statement regarding the unobviousness of the mixture of icIL-1ra-II proteins recited in the claims.

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Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 9-12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Colotta et al. This rejection is respectfully traversed.

The Colotta reference is the same as the Muzio et al. 1995 reference (WO 96/12022) cited in the present specification on page 2, lines 12-13. The protein disclosed in the Colotta reference was identified by using polyclonal antibodies on total cell lysates and supernatants from the COS cell transfection, and the protein sequence was deduced from the determined nucleotide sequence of the clones. The sequence of a protein however is only certain once the isolated protein is sequenced. The sequence deduced from a DNA sequence is only considered to be deduced and nothing more. Thus, from merely the DNA sequence, it is not possible to know with certainty that the clone sequenced expresses a mixture of icIL-1ra-II proteins. Accordingly, unlike the present invention, Colotta does not teach an isolated mixture of icIL-1ra-II proteins as presently claimed and therefore cannot anticipate the present invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their

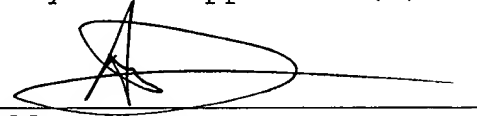
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allowance. Favorable consideration and allowance are earnestly urged.

Respectfully submitted,

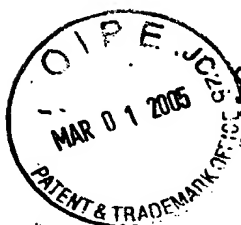
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Sample #5 (Solution) Exp 100

01/11/98
105/198Ron Pinkus, Ph.D.
Protein Biochemistry

Fax :

089302013

| Cycle | Res. | | |
|-------|------|------|-----|
| 1 | - | Ala | met |
| 2 | - | Leu | Ala |
| 3 | - | Ala | Leu |
| 4 | - | Asp | Ala |
| 5 | - | Leu | Asp |
| 6 | - | Tyr | Leu |
| 7 | - | Glu | Tyr |
| 8 | - | Glu | Glu |
| 9 | - | Gly | Glu |
| 10 | - | Gly | Glu |
| 11 | - | Gly | Glu |
| 12 | - | Gly | Glu |
| 13 | - | Gly | Glu |
| 14 | - | Gly | Glu |
| 15 | - | Glu | Asp |
| 16 | - | Gly | ASN |
| 17 | - | Glu | Ala |
| 18 | - | Asp | Asp |
| 19 | - | ASN | Ser |
| 20 | - | Abol | Lys |

Results of #5 Solution

1 the major form is

+2

2 than +1

3 than +5

+2 > +1 > +5

Conclusion

~~there~~It is possible for the
existence of Protease

to do keep 42 at all time

Most important: It is ic-L1 va
and only him

אילנה כלזר

22.07.2001

חתימה